IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, vs. XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	Civil Action No. 1:23-cv-00707

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

For decades, Medicare has relied on a market-based system for reimbursing drug purchases, helping to make America the world leader in pharmaceutical research and development. This system has benefitted patients (who receive cutting-edge medicines that extend and enhance their lives), manufacturers (who earn competitive returns for successful products), and providers (who receive reimbursement for administering innovative drugs).

In the Inflation Reduction Act of 2022 (IRA), Congress attempted to replace that time-tested system with government-dictated prices. If enacted forthrightly, this new scheme would have come at a high political cost because price controls harm innovation and patient care. To avoid the likely backlash, Congress adopted a complex and entirely novel structure that, at every turn, seeks to avoid accountability and oversight, obscuring the fact that drug prices are being dictated by government *fiat*.

Here is how the so-called "Drug Price Negotiation Program" (Drug Pricing Program or Program) works. Contrary to its name, the Program involves no genuine "negotiation" at all. Instead, it *compels* manufacturers to accept prices that the Centers for Medicare & Medicaid Services (CMS), a sub-agency of the Department of Health and Human Services (HHS), unilaterally chooses. The law establishes a price ceiling that may not be exceeded, while affording the agency complete discretion to choose as *low* a price as it wants: The agency could decide that an innovative, lifesaving medicine that cost $10 billion to develop is worth just $1 per dose.

In any genuine negotiation, the seller would be free to decline to sell at such an unfair price. But Congress blocked that option. If manufacturers do not agree to participate in the sham "negotiation," or do not accede to whatever price the agency ultimately demands, they are subject to a crippling "excise tax." This supposed "tax" is staggering, starting at a multiple of daily revenues and rapidly escalating to *19 times* the manufacturer's *total U.S. revenues* for the drug in

question (not merely its Medicare revenues). The manufacturer's only alternative is to exit Medicare and Medicaid altogether, not just for the drug in question, but for *all* the manufacturer's drugs—depriving patients nationwide of access to critical medicines and foreclosing nearly half the U.S. drug market. That faux "negotiation," backed by the very real threat of a crippling "tax," serves no legitimate purpose other than obscuring Congress's price-fixing scheme.

Next, Congress insulated this scheme from meaningful accountability. On the front end, the agency claims that it need not engage in notice-and-comment rulemaking regarding the Program's administration. The agency accordingly has already made key implementation decisions—including decisions that stretch the Program beyond the statutory text—without accounting for the views of affected parties. And on the back end, the IRA's text purports to foreclose altogether administrative and judicial review of critical agency decisions. As a result, the agency can decree any price it wants for a manufacturer's drug and then force the manufacturer to "agree" that it is "fair," without any meaningful ability to reach a different deal, walk away from negotiations, or challenge how the agency reached its decision. Patients and providers are shut out as well, even though government-set prices determine providers' reimbursement rates and patients' access to innovative treatments. Concealing its true operation through euphemisms, and totally lacking in accountability, the IRA is a law like none other.

These unprecedented aspects of the Drug Pricing Program render it unconstitutional in at least three ways. *First*, Congress delegated unconstrained authority to the agency, in violation of the separation of powers and the nondelegation doctrine. Price-setting statutes have a historical pedigree, but the IRA is unprecedented because it vests the agency with complete discretion to set prices as low as it wants (regardless of whether the prices are reasonable). Further, it leaves key interpretive and policy decisions to the agency's unfettered choice—essentially allowing the

agency to rewrite the statute as it sees fit, without meaningful judicial oversight.

Second, the excise-tax penalty violates the Eighth Amendment's Excessive Fines Clause. Failing to agree on a negotiated price ordinarily is not considered unlawful or even wrongful conduct. But if a manufacturer fails to agree to the government-imposed price for one of its products, the manufacturer is penalized with a daily excise tax—on *all* of its nationwide sales of the product, not just Medicare sales—that starts unbearably high and quickly escalates into the stratosphere. Indeed, the penalty is so onerous that the Joint Committee on Taxation and the Congressional Budget Office (CBO) both estimated that it will raise "no revenue" because no manufacturer could ever afford to pay it.

Third, exempting key agency implementation decisions from public input and insulating them from judicial review violates the Fifth Amendment's Due Process Clause. The law directly implicates patients, whose access to essential drugs may be thrown into jeopardy; manufacturers, who have invested billions developing drugs that may suddenly be rendered unprofitable; and providers, who face slashed reimbursement rates that could drive them out of business. Yet the agency insists that the IRA gives interested stakeholders *no* meaningful notice-and-comment rights (on the front end) or ability to challenge legally erroneous decisions in court (on the back end).

If allowed to stand, this law will dramatically slow innovation, reduce the availability of new medicines, and undermine public health, causing grave harm to patients, pharmaceutical manufacturers, and healthcare providers. The National Infusion Center Association (NICA), the Global Colon Cancer Association (GCCA), and Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully ask this Court to grant summary judgment, to declare the Drug Pricing Program unconstitutional, and to enjoin its implementation.

BACKGROUND

A. Pharmaceutical Innovation Requires Investment in Research and Development

The process of developing new drugs is lengthy, risky, and expensive. *See* Ex. 1, Expert Decl. of Craig Garthwaite ¶¶ 16–29; Ex. 2, Decl. of Adam Gluck ¶ 10. Today, companies are developing hundreds of new medicines to treat cancers, pediatric conditions, and rare diseases. *See* PhRMA, *Medicines in Development 2021 Report: Rare Diseases* 1 (Dec. 2021), https://bit.ly/3go50j8; PhRMA, *Medicines in Development 2022 Report: Women* 2 (Mar. 2022), https://bit.ly/3EzupyG; Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Report: Children* 1 (Jan. 2020), https://onphr.ma/2PSX4FN. Researchers also are working on hundreds of novel cell and gene therapies. *See* Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Update: Cell and Gene Therapy* 1–2 (Feb. 2020), https://onphr.ma/3fY6wSX. And—of particular importance to the older population Medicare covers—companies are developing cutting-edge treatments for Alzheimer's Disease. *See* PhRMA, *Continued Progress Toward New Treatments for Alzheimer's Disease Provides Hope to Millions* 1 (Mar. 2022), https://onphr.ma/42zq8pt. Recent studies indicate that, to develop just one new drug, manufacturers spend an average of over $2 billion. *See* Garthwaite Decl. ¶ 25. Some drugs for complex conditions require over $10 billion in research and development investment. *See* Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., no. 105, at 3–4, (Apr. 27, 2016), https://bit.ly/2PWRKRC. And the necessary investments are increasing. Over the last 60 years, drug research and development costs have risen 8.6% annually, even after adjusting for inflation. *See id.* at 3.

Manufacturers also face long odds. Only one in 5,000 compounds that enters preclinical testing will achieve FDA approval, a failure rate of 99.98%. *See* Sandra Kraljevic et al.,

Accelerating Drug Discovery, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK. Of the therapies approved for patient use, only one-third will even cover their development costs, much less provide returns sufficient to allow for continued investment and innovation. *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7 (2008), http://bit.ly/3UR06de.

Notwithstanding the low success rate, the U.S. biopharmaceutical industry invested an estimated $122 billion on research and development in 2020 alone, representing almost 60% of global pharmaceutical research and development spending. *See* Garthwaite Decl. ¶¶ 10, 16. To justify this level of investment, the expected returns for medicines that do make it to market must be high enough to counterbalance the substantial likelihood of failure. And manufacturers must make investment decisions based on predictions about expected returns a decade or more before the product will launch and begin earning revenues. *See id.*; Gluck Decl. ¶ 11.

Successful pharmaceutical innovation benefits not just manufacturers, but providers and patients as well. Providers are in the business of extending and improving patients' lives by administering treatments that pharmaceutical manufacturers make—including innovative new drugs and therapies. Administering innovative drugs and biologics and obtaining reimbursement based on market prices is the foundation of how providers keep their doors open and serve their patients' needs. Ex. 3, Decl. of Brian Nyquist ¶¶ 9–10. Patients, in turn, depend on pharmaceutical innovation to save, extend, and improve their lives. *See* Ex. 4, Decl. of Andrew Spiegel ¶¶ 9–13, 19; Nyquist Decl. ¶¶ 4, 6.

B. Medicare Traditionally Encouraged Pharmaceutical Innovation

A key driver of pharmaceutical innovation has been the market-based reimbursement traditionally afforded by Medicare. "Medicare stands as the largest federal program after Social Security," providing "health insurance for nearly 60 million aged or disabled Americans, nearly

one-fifth of the Nation's population." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019); *see* Garthwaite Decl. ¶ 87. As relevant here, Medicare includes two major prescription drug programs. First, Medicare Part B covers medically necessary and preventative healthcare services, including drugs administered by a physician. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A); Garthwaite Decl. ¶ 33. Medicare Part B is administered by CMS and, with certain exceptions, has long reimbursed providers based on market prices. Medicare Part B reimbursement rates generally reflect the drug's "average sales price"—which incorporates the volume-weighted average of all manufacturer sales prices to U.S. purchasers, with certain exceptions—plus a specified percentage (currently 6%). *See* 42 U.S.C. § 1395w-3a; Garthwaite Decl. ¶¶ 36, 38.

Second, Medicare Part D allows Medicare beneficiaries to enroll in privately operated plans covering self-administered prescription drugs. *See* 42 U.S.C. § 1395w-102; Garthwaite Decl. ¶ 35. Drug prices in Part D also are market-based. Part D plans are administered by private plan sponsors, which negotiate prices with manufacturers. *See id.* ¶¶ 36–37. Moreover, the Part D statute provides that, "[i]n order to promote competition under [Part D]," HHS and CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors." 42 U.S.C. § 1395w–111(i); *see* Garthwaite Decl. ¶ 49. For decades, then, Medicare has encouraged a market-driven approach that has fostered incredible innovation.

Although Medicare's market-based approach benefits patients globally, it helps Americans most directly. Manufacturers generally launch new drugs in the United States first; accordingly, U.S. patients are often the first to receive lifesaving pharmaceuticals. For example, 80% of medicines approved by the FDA in 2021 were available in the United States before any other country. *See* Garthwaite Decl. ¶ 10. Foreign countries with drug-price controls have seen drastic reductions in research and investment, as well as delays in patients' access to advanced treatments.

See Joe Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Info. Tech. & Innovation Found. (Sept. 9, 2019), https://bit.ly/3fSIysc; PhRMA, *Global Access to New Medicines Report* 8, 11–36 (Apr. 2023), https://bit.ly/3OR7GEx.

C. The IRA Upends Medicare's Market-Based Reimbursement Mechanisms

The IRA upends Medicare's market-based system. The statute directs HHS to establish a "Drug Price *Negotiation* Program." 42 U.S.C. § 1320f(a) (emphasis added). But in reality, the Program empowers HHS to control drug prices not by negotiation, but by administrative *fiat*.

1. HHS Ranks and Selects "Negotiation-Eligible Drugs"

Beginning in 2023, the IRA directs HHS to rank "negotiation-eligible drugs" based on Medicare's "total expenditures" for them (first in Part D, later in Part B as well) over a specified twelve-month period. *Id.* § 1320f–1(b)(1)(A). Drugs with the highest total expenditures during the specified period are to be ranked the highest. *Id.*

The "negotiation-eligible drugs" that HHS must rank encompass many of the most innovative drugs and biological products available. The IRA defines "negotiation-eligible drugs" as the 50 "qualifying single source drugs" with the highest total expenditures under Parts B and D. *Id.* § 1320f–1(d)(1). A "qualifying single source drug" is defined as one that (1) is marketed under a new drug application or a biologics license application, (2) has been approved by FDA for at least 7 years for drugs or 11 years for biological products, and (3) is not the reference drug for an approved and marketed generic drug or biosimilar product. *Id.* § 1320f–1(e)(1).

Once "negotiation-eligible" drugs have been identified and ranked, the IRA directs HHS to "select" an increasing number of the highest-ranked drugs for negotiation and "publish a list of [them]." *Id.* § 1320f–1(a). Part D drugs will be selected starting in 2023, with "maximum fair prices" taking effect in 2026; Part B drugs are added to the selection process beginning in 2026, with maximum prices taking effect in 2028. *Id.* § 1320f–1(a)(1), (3). Ten Part D drugs will be

selected for 2026, fifteen Part D drugs for 2027, fifteen Part D and Part B drugs for 2028, and twenty Part D and Part B drugs for 2029 and each year thereafter. *Id.* § 1320f–1(a)(1)–(4). This process is cumulative: A selected drug remains selected until HHS determines that an approved generic or licensed biosimilar has been marketed. *Id.* § 1320f–1(c)(1).

HHS must publish the first list of selected drugs by September 1, 2023. *Id.* § 1320f(d)(1), 1320f–1(a)(1). At least one drug manufactured by a member of PhRMA will be included on the first list, as well as subsequent lists. *See* Ex. 5, Decl. of Kristen Bernie ¶¶ 13–15; Garthwaite Decl. ¶ 70; Ex. 6, Decl. of Patrick Costello ¶ 19; Gluck Decl. ¶ 9.

2. HHS Sets "Maximum Fair Prices" Through Sham "Negotiations"

Once drugs are ranked and selected, the IRA directs HHS to "enter into agreements with manufacturers" whereby the parties "negotiate to determine (and … agree to) a maximum fair price." 42 U.S.C. § 1320f–2(a)(1). Manufacturers of drugs included on the first list of selected drugs must enter into these "agreements" by October 1, 2023. *Id.* §§ 1320f(d)(2)(A), 1320f–2(a). The ensuing "negotiations" then must conclude by August 1, 2024. *Id.* §§ 1320f(d)(5), 1320f–3(b)(2)(E).

To conduct the "negotiations," the statute directs HHS to "develop and use a consistent methodology and process … that aims to achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f–3(b)(1). The "negotiation" process includes an HHS "offer," a manufacturer "counteroffer," and an HHS "[r]esponse." *Id.* § 1320f–3(b)(2)(C)–(D). But that is where any resemblance to genuine negotiation ends.

To begin with, HHS can demand any information it wants on pain of massive penalties. The statute commands manufacturers to give HHS a host of closely guarded trade secrets and other proprietary information, including the manufacturer's research and development costs, market data, and costs of production and distribution. *Id.* §§ 1320f–2(a)(4)(B), 1320f–3(e)(1).

Manufacturers also must "compl[y] with" whatever *other* requirements HHS deems "necessary for purposes of administering the program." *Id.* §§ 1320f–2(a)(5), 1320f–6(c). These onerous requirements are enforced by $1 million-per-day civil penalties—*plus* the crippling excise tax discussed below. *Id.* §§ 1320f–2(a)(4)–(5), 1320f–6(c); 26 U.S.C. § 5000D(b)(4).

The IRA then sets no meaningful constraints on what prices HHS can mandate. With one minor exception, the statute does not limit how *low* a price HHS can demand. 42 U.S.C. § 1320f–3(b)(2)(F). But it does place a "ceiling" on how *high* a price HHS can offer. *Id.* § 1320f–3(c). For the Program's first year, the ceiling is calculated as a percentage of a baseline price (generally, the inflation-adjusted non-federal average manufacturer price in 2021). The ceiling ranges from 75 percent of that benchmark for recently approved drugs, down to just 40 percent for drugs that have been approved for over 16 years. *Id.* § 1320f–3(b)(2)(F), (c)(1)(C)(i). In other words, the IRA mandates a first-year *minimum* discount of 25-to-60 percent. For subsequent years, the ceiling can be even more restrictive—the statute directs HHS to use either the calculation above or an alternative calculation if it is lower. *Id.* § 1320f–3(c)(1)(C)(ii).

Below the applicable "ceiling," HHS has free rein to set prices as it pleases. At most, HHS must "consider" specified "factors," including research and development costs, production and distribution costs, prior federal financial support, data on patents and regulatory exclusivities, market data and revenue and sales volume data, and information about alternative treatments. *Id.* § 1320f–3(e). Yet the IRA sets no criteria for how to weigh these considerations, nor does it require HHS to disclose in any meaningful way how it balanced those factors in setting prices. And the statute's low-ceiling, no-floor design gives HHS every incentive to drive prices as low possible.

Once HHS has imposed a "maximum fair price" and that price becomes effective, the manufacturer must provide "access to such price to" a wide array of individuals, pharmacies,

providers, and other entities participating in Medicare. *Id.* § 1320f–2(a)(1). Manufacturers that fail to do so must pay a penalty of *ten times* the difference between the price charged and the price imposed by HHS, multiplied by the number of units sold. *Id.* § 1320f–6(b).

3. Noncompliant Manufacturers Must Pay a Crippling "Excise Tax"

The hammer the IRA uses to force manufacturers to "agree" to a "maximum fair price" is a so-called "excise tax." In ordinary negotiations, parties that fail to reach agreement regarding price can simply walk away. *See* Garthwaite Decl. ¶¶ 42, 81. But under the IRA, manufacturers cannot do that. Instead, the statute imposes a steep penalty for every day the manufacturer has not, by the applicable statutory deadline, (1) entered into an "agreement" to negotiate a maximum fair price for a negotiation-eligible drug, (2) "agreed" to a maximum fair price, or (3) submitted the information HHS demands for the "negotiation" process. 26 U.S.C. § 5000D(b). Congress labeled this penalty an "excise tax," but it is intended to coerce rather than raise revenue.

The size and scope of this "tax" is staggering. It applies to *all* U.S. sales of the drug in question, not just Medicare sales. *See id*. The tax is calculated based on a formula representing an "applicable percentage" of the drug's total cost (price plus tax). *Id.* § 5000D(d). The applicable percentage starts at 65% and then increases 10% for each quarter of noncompliance until it reaches 95%. *Id.* As the Congressional Research Service explained, "[t]he excise tax rate" thus "range[s] from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance." Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)*, 4 (Aug. 10, 2022), https://bit.ly/3sbHYBy. In other words, the tax *starts* at nearly double the manufacturer's total daily U.S. revenue for the drug, and quickly escalates to *19 times* revenue. A summary of predecessor legislation described the excise tax as a "steep, escalating penalty." Title Summary, H.R. 3, at 1 (2022). Indeed, though the statute calls it a "tax," both the Joint Committee on Taxation and CBO estimated that the tax would raise "no revenue" because no

manufacturer could ever afford to pay it. Joint Comm'n on Tax'n, *Estimated Budget Effects of the Revenue Provisions of Title XIII – Committee on Ways and Means, of H.R. 5376, The "Build Back Better Act,"* at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd; *see* CBO, *Estimated Budgetary Effects of Public Law 117-169*, at 5 (Sept. 7, 2022), https://bit.ly/3JOiq3r (similar). Instead, manufacturers will have no choice but to "agree" to whatever "maximum fair price" HHS demands.

The IRA provides that the excise-tax penalty may be "[s]uspen[ded]," but only if the manufacturer terminates three types of agreements with HHS. 26 U.S.C. § 5000D(c). Terminating those agreements would eliminate coverage under Medicare Part D, Medicare Part B, *and* Medicaid—not just for the manufacturer's drugs subject to the IRA's Drug Pricing Program, but for *all* of the manufacturer's drugs. *See id.*; 42 U.S.C. § 1396r-8(a)(1).

Withdrawing from Medicare and Medicaid altogether is not feasible for manufacturers. To begin with, "[t]he consequence of" withdrawing from Medicare and Medicaid "would be catastrophic for almost any manufacturer." Garthwaite Decl. ¶ 84; *see id.* ¶¶ 85–88. "Through Medicare and Medicaid, [the federal government] pays for almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Medicare and Medicaid account for a hefty portion of many manufacturers' revenue. *See* Bernie Decl. ¶ 11; Garthwaite Decl. ¶ 87; Costello Decl. ¶ 20; Gluck Decl. ¶ 13. In addition, withdrawing from Medicare and Medicaid would cause millions of patients to lose access to medicines they depend on. Pulling the rug out from under patients who have come to rely on medicines for a course of therapy would raise ethical concerns and would be "anathema" to manufacturers' "mission." Gluck Decl. ¶ 13; *see* Costello Decl. ¶ 20; Garthwaite Decl. ¶ 88.

Even if a manufacturer were able, let alone willing, to shoulder those financial, ethical, and reputational costs, the IRA delays manufacturers' ability to exit from Medicare Part D—and thus

compels them to participate—for between 11 and 23 months. *See* 42 U.S.C. §§ 1395w–114a(b)(1)(C)(ii), 1395w–114c(b)(4)(B)(ii), 1395w–153(a)(1). CMS recently issued nonbinding guidance stating that, if manufacturers withdraw, the agency will take administrative actions to reduce that exit delay down to 30 days. *See* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance for Initially Price Applicability Year 2026* [hereinafter *Revised Guidance*], at 120–21 (June 30, 2023), https://bit.ly/3JLSSUH. But the agency's statutory basis for those promised administrative actions is dubious at best, and manufacturers cannot rely on them—particularly since the agency could seemingly change its mind at any time. *See infra* Part I.

4. The IRA Limits Notice-and-Comment Rulemaking and Judicial Review

Despite the Drug Pricing Program's unprecedented burdens on manufacturers and serious repercussions for providers and patients, affected parties have no say in how HHS implements key parts of the Program, and they are deprived of legal recourse regarding numerous critical decisions.

On the front end, before implementation decisions are made, there is no right to participate in the implementation process. The Administrative Procedure Act sets forth general requirements for notice-and-comment rulemaking, which the Social Security Act requires HHS to follow in substantive rulemaking under Medicare. *See* 5 U.S.C. § 553(b), (c); 42 U.S.C. § 1395hh. The IRA, however, provides that HHS "shall implement [the Drug Pricing Program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." *Id.* § 1320f note. CMS has read that language to exempt the Drug Pricing Program from notice-and-comment requirements during the Program's formative years. *See* CMS, *Medicare Drug Price Negotiation Program: Initial Memorandum for Initial Price Applicability Year 2026* [hereinafter *Initial Guidance*] at 2 (Mar. 15, 2023), https://bit.ly/3m0cDPG; *Revised Guidance* at 8–11.

On the back end, after implementation decisions are made, the IRA purports to insulate critical decisions from review. For example, the statute provides that "[t]here shall be no

administrative or judicial review" of many key HHS determinations, including "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f–7(2)–(3).

D. CMS Implements the IRA Through Guidance

In March 2023, CMS issued initial guidance on the Drug Pricing Program for 2026. The Initial Guidance confirmed CMS's view that the Program "is not subject to the notice-and-comment requirement of the Administrative Procedure Act or the Medicare statute." *Initial Guidance* at 2. And while CMS "voluntarily" solicited comments on some aspects of the Initial Guidance, it adopted other aspects as final. The aspects finalized without notice-and-comment encompass some of the Program's most critical elements, including "the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs." *Id.* at 4. CMS also claimed the unconditional right to "make changes to any policies, including policies on which CMS has not expressly solicited comment." *Id.* at 2.

In June 2023, CMS issued revised Program guidance for 2026. Among other changes, CMS altered some aspects of the Initial Guidance that it had previously issued as "final," without any solicitation of comments. *See Revised Guidance* at 97. As noted, the Revised Guidance also discusses a mechanism to expedite manufacturers' exit from Medicare Part D, purportedly reducing the 11-to-23 month statutory delay to 30 days. *See id.* at 120–21.

ARGUMENT

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Here, Plaintiffs are entitled to judgment as a matter of law on all three of their claims. The Drug Pricing Program violates the separation of powers and the nondelegation doctrine; it violates the Eighth

Amendment's Excessive Fines Clause; and it violates the Fifth Amendment's Due Process Clause.

I. THE IRA VIOLATES THE SEPARATION OF POWERS AND THE NONDELEGATION DOCTRINE

Article I, section 1 of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." Congress accordingly may not "delegate to [other branches] powers which are strictly and exclusively legislative." *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42 (1825). Indeed, "[t]hat congress cannot delegate legislative power to the [executive branch] is a principle universally recognized as vital to the integrity and maintenance of the system of government ordained by the constitution." *Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892). The Supreme Court has twice struck down statutes as violating these principles. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935); *Panama Ref. Co. v. Ryan*, 293 U.S. 388 (1935). The Fifth Circuit did so again just last year. *See Jarkesy v. SEC*, 34 F.4th 446, 459–63 (5th Cir. 2022), *cert. granted*, No. 22-859, 2023 WL 4278448 (June 30, 2023). As the Supreme Court recently unanimously confirmed, Congress may not "transfer[] its legislative power to another branch." *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019) (plurality op.); *see id.* at 2130 (Alito, J., concurring in the judgment) (similar); *id.* at 2133–35 (Gorsuch, J., dissenting) (similar).

The nondelegation doctrine reflects larger separation-of-powers principles. The Framers "divided the powers of the new Federal Government into three defined categories, Legislative, Executive, and Judicial." *Seila L. LLC v. CFPB*, 140 S. Ct. 2183, 2202 (2020) (quotation marks omitted). Beyond that, "the Framers bifurcated the federal legislative power into two Chambers: the House of Representatives and the Senate, each composed of multiple Members and Senators." *Id.* at 2203. "The resulting constitutional strategy is straightforward: divide power everywhere except for the Presidency, and render the President directly accountable to the people through regular elections." *Id.* Congress "contravenes this carefully calibrated system" if it "vest[s] significant

governmental power in the hands of a single individual accountable to no one." *Id.* "[A]ccountability evaporates if a person or entity other than Congress exercises legislative power." *Jarkesy*, 34 F.4th at 460.

The IRA violates the separation of powers by delegating to HHS unconstrained discretion to set Medicare drug prices as low as it chooses. While the statute directs HHS to "consider" certain "factors," it provides *no* guidance on how the agency must weigh those factors and sets *no* concrete limits on the agency's ultimate discretion—other than a minimum discounted "ceiling" price the agency must achieve and a directive to "achieve the *lowest* maximum fair price." 42 U.S.C. § 1320f–3(b)(1), (c), (e) (emphasis added). Unlike historical federal price-setting statutes, the IRA is not limited to wartime exigencies or the unique problems of common carriers; and because it imposes no floor or other meaningful constraint on prices, the IRA does not require prices to be "just and reasonable," as previous price-control statutes have done. *See, e.g.*, Pub. L. No. 421, §§ 2, 302, 56 Stat. 23 (1942); 15 U.S.C. § 717c; 16 U.S.C. § 824d. Instead, the IRA gives HHS unconstrained authority to replace market prices for Medicare's most beneficial drugs with lower prices of the agency's unfettered choosing. But Congress cannot commit to an agency's untrammeled discretion command-and-control authority over vast swaths of the economy. *See Jarkesy*, 34 F.4th at 462.

Furthermore, key terms in the IRA are sufficiently open-ended to allow HHS to claim authority to make fundamental policy choices—essentially allowing the agency to rewrite the statute as it sees fit. In addition to its already expansive price-setting authority for negotiation-eligible drugs, CMS also has claimed authority to determine when multiple products qualify as one qualifying single source drug for purposes of determining whether the products qualify for price controls in the first place. *See Revised Guidance* at 11–12. CMS likewise reads the statute not to specify what it means for a generic drug or biosimilar product to be "marketed," such that the reference drug or biological

product would not be negotiation-eligible. *See id.* at 72–78. And CMS has asserted wide discretion to determine what is included in the "total expenditures" that determine HHS's rankings. *See id.* at 97 & n.29; 88 Fed. Reg. 22,120, 22,260 (Apr. 12, 2023). While these issues encompass only parts of the IRA's expansive Drug Pricing Program, they are not the sort of minor matters where an administrative agency may be empowered to "fill up the details." *Wayman*, 23 U.S. (10 Wheat.) at 43. They are "important subjects, which must be entirely regulated by the legislature itself." *Id.*

Where Congress "mandate[s] compliance with … requirements for notice and comment," that may "weigh[] in favor of [upholding] a delegation." *United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (citation omitted). But the IRA conspicuously *lacks* that procedural safeguard. In the Program's formative years, the statute does not require notice-and-comment rulemaking—or even the solicitation of *any* external input. And the draconian excise tax prevents manufacturers from protecting themselves against arbitrary agency decision-making during the "negotiation" process.

Finally, "judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." *Id.* Congress thus traditionally avoids nondelegation problems by "provid[ing] an administrative agency with standards guiding its actions such that a court could ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989) (quotation marks omitted). But here, the IRA purports to insulate critical agency decisions from judicial review. *See* 42 U.S.C. § 1320f–7.

The elimination of judicial review in the Drug Pricing Program presents a serious nondelegation problem. In *Touby v. United States*, 500 U.S. 160 (1991), for example, the Supreme Court upheld a delegation scheme limiting judicial review, but only because the statute merely "postpone[d] legal challenges … until the administrative process ha[d] run its course." *Id.* at 168. Here, the IRA purportedly *eliminates* judicial review over critical administrative decisions. Giving

HHS unreviewable authority to resolve basic statutory-interpretation questions is tantamount to permitting the agency to rewrite the statute—a *legislative* function. "[J]udicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." *Id.* at 170 (Marshall, J., concurring).

Without judicial constraint, HHS could attempt—with impunity—to simply ignore binding statutory constraints on its price-setting authority. For example, HHS could select a product for negotiation even though it is *not* negotiation-eligible under the statute. If the manufacturer challenged that unlawful decision in court, HHS could respond by citing the IRA's judicial review bar, which provides that "[t]here shall be no … judicial review" of "[t]he selection of drugs" or "the determination of qualifying single source drugs." 42 U.S.C. § 1320f–7(2)–(3). This is just one statutory requirement HHS could ignore while claiming that no judicial review is available to correct its overreach. HHS has a "capacious portfolio of authority" under the IRA, which makes "[t]he constitutional problem … more acute." *Cmty. Fin. Servs. Ass'n of Am., Ltd. v. CFPB*, 51 F.4th 616, 640 (5th Cir. 2022), *cert. granted*, 143 S. Ct. 978 (2023).

Standing alone, each of these defects undermines separation-of-powers principles. Taken together, they create a "novel structure," *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 496 (2010), that concentrates "significant governmental power" in an administrative agency "accountable to no one," *Seila*, 140 S. Ct. at 2203, to set prices for nearly half of nationwide prescription drug sales. That result is fatal to the Drug Pricing Program. "Perhaps the most telling indication of a severe constitutional problem with an executive entity is a lack of historical precedent to support it." *Id.* at 2201 (cleaned up). Plaintiffs are aware of no other statute that grants such sweeping power to an administrative agency while *also* barring both front-end input via notice-and-comment rulemaking *and* back-end accountability via judicial review.

II. THE IRA VIOLATES THE EXCESSIVE FINES CLAUSE

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." The Excessive Fines Clause "limits the government's power to extract payments, whether in cash or in kind, as punishment for some offense." *United States v. Bajakajian*, 524 U.S. 321, 328 (1998) (citation omitted). It applies not only to criminal fines but also to civil fines designed "in part to punish." *Austin v. United States*, 509 U.S. 602, 610 (1993); *see Hudson v. United States*, 522 U.S. 93, 103 (1997). "[T]he touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: the amount of the [fine] must bear some relationship to the gravity of the offense that it is designed to punish." *Bajakajian*, 524 U.S. at 334.

The IRA's "excise tax" triggers and violates the Excessive Fines Clause. It is designed to punish noncompliance with the IRA's sham negotiation process, and it is wildly disproportionate to the "offense" of refusing to agree that a government-dictated price is "fair."

A. The IRA's Excise Tax Is Punitive

The IRA's excise tax triggers the Excessive Fines Clause because it is punitive in nature. In assessing whether a "tax" operates as a penalty, the Supreme Court has adopted a "functional approach," under which labels are not dispositive. *NFIB v. Sebelius*, 567 U.S. 519, 565 (2012). In the related context of the Double Jeopardy Clause, courts determine whether a tax is punitive by considering its size and purpose. *See Dep't of Revenue of Mont. v. Kurth Ranch*, 511 U.S. 767, 780 (1994); *Dye v. Frank*, 355 F.3d 1102, 1105 (7th Cir. 2004). And "[i]t matters not whether the scheme has a remedial purpose, even a predominantly remedial purpose" because "the Excessive Fines Clause applies to *any* statutory scheme that serves *in part* to punish." *Tyler v. Hennepin Cnty.*, 143 S. Ct. 1369, 1381 (2023) (Gorsuch, J., concurring) (cleaned up).

Here, the IRA's excise tax is unquestionably punitive. A summary of predecessor

legislation accurately described it as a "steep, escalating *penalty*." Title Summary, H.R. 3, at 1 (2022) (emphasis added). Not only does the statutory scheme serve "in part" to punish, that appears to be its *sole* purpose: Prior to the IRA's passage, the Joint Committee on Taxation and the CBO both told Congress that the tax would raise no revenue *at all*, since no rational manufacturer would ever dare trigger it. *See supra*, at 10. Instead, the tax serves to coerce manufacturers into participating in the IRA's sham negotiation process and, failing that, to punish them harshly. Indeed, the relevant section of the tax code is entitled, "Designated drugs during *noncompliance* periods." 26 U.S.C. § 5000D (emphasis added); *see id.* § 5000D(b) (subparagraph entitled "Noncompliance periods"). "Deter[ring]" noncompliance "has traditionally been viewed as a goal of punishment." *Bajakajian*, 524 U.S. at 329. At the very least, the excise tax "cannot fairly be said *solely* to serve a remedial purpose." *Tyler*, 143 S. Ct. at 1381 (Gorsuch, J. concurring) (cleaned up). Therefore, "the Excessive Fines Clause applies." *Id.*

The sheer size of the tax penalty further demonstrates its punitive nature. The tax rate starts at 186% of a drug's total U.S. revenues, and, after 271 days, reaches 1,900%. 26 U.S.C. § 5000D(b)(1)–(4). That enormous levy would cause significant financial harm to manufacturers. *See* Garthwaite Decl. ¶¶ 66, 84–87; Bernie Decl. ¶ 10. Indeed, for every $1 billion in annual net revenues for a drug, a manufacturer would incur *$19 billion* in penalties after a year. Garthwaite Decl. ¶ 66. And if the drug "accounts for approximately 13 percent or more of its manufacturer's total net revenues, applying the excise tax over a full year . . . would result in an excise tax liability of 100 percent of the manufacturer's total net revenues." *Id.* ¶ 85. By any conceivable measure, that is an "exceedingly heavy burden," *NFIB*, 567 U.S. at 565, confirming that the tax is punitive and does not "solely" serve a remedial purpose, *Tyler*, 143 S. Ct. at 1381 (Gorsuch, J. concurring). *See Bajakajian*, 524 U.S. at 337–40 (concluding that a significantly less onerous excise tax was

grossly disproportionate and punitive).

While the excise tax directly punishes noncompliant manufacturers, its harms extend more broadly. Without it, manufacturers could more effectively resist lowball "offers" from HHS that do not align with a medicine's value, allowing prices and reimbursement rates to continue to reflect market forces. In other words, the excise tax is an integral part of the IRA's scheme for imposing government-dictated prices. As such, the excise tax not only punishes manufacturers, but also reduces reimbursements to providers and limits patients' access to innovative treatments.

B. The IRA's Excise Tax Is Grossly Disproportionate

The IRA's excise tax violates the Excessive Fines Clause because it is wildly disproportionate to the "offense" it seeks to punish. While the Eighth Amendment does not require strict proportionality between the punishment and the gravity of the offense, it forbids "gross disproportionality." *Bajakajian*, 524 U.S. at 336. The Supreme Court has considered three general criteria: "the degree of the defendant's reprehensibility or culpability; the relationship between the penalty and the harm to the victim caused by the defendant's actions; and the sanctions imposed in other cases for comparable misconduct." *Cooper Indus. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 435 (2001) (citations omitted). Federal courts have applied these factors to many kinds of penalties. *See, e.g.*, *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1314–16 (11th Cir. 2021) (treble damages and statutory penalties); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 387–90 (4th Cir. 2015) (punitive damages and civil penalties). These factors establish that the excise-tax penalty is grossly disproportionate to the "offense" of failing to participate in the IRA's compelled-negotiation process.

First, the supposed "offense" being punished—a manufacturer's refusal to express its agreement to a price imposed by HHS—does not entail any "reprehensibility or culpability." *Cooper Indus.*, 532 U.S. at 435. Noncompliant conduct under the IRA involves no "threat of

violence," "trickery," or "deceit," nor does it involve "indifference to or reckless disregard for the health and safety of others." *BMW of N. Am. v. Gore*, 517 U.S. 559, 576 (1996). Indeed, failing to agree on a price for the lawful sale of beneficial medicines ordinarily is not even considered wrongful, much less unlawful. At a minimum, this conduct is less culpable than that at issue in *Bajakajian*, where the Supreme Court held that forfeiting $357,444 in currency was grossly disproportionate to the offense of failing to report that same amount of currency to customs inspectors. *See* 524 U.S. at 337–40. The Court held that the defendant had "a minimal level of culpability" because his "crime was solely a reporting offense," since "[i]t was permissible to transport the currency out of the country so long as he reported it." *Id.* at 337, 339. Here, a manufacturer's refusal to accept an offer it views as unfairly low is not culpable at all.

Second, there is no reasonable relationship between the size of the penalty and any harm caused. As in *Bajakajian*, the "offense" at issue is "unrelated to any other illegal activities," it "affect[s] only … the Government," and it does not involve "fraud on the United States." *Id.* at 338–39. Even if the government has an interest in ensuring that drugs are sold for no more than HHS's mandated price, the tax vastly exceeds any alleged harm. A noncompliant manufacturer faces a penalty of multiple times its *total daily revenues* for *all U.S. sales* of the drug—a figure that dwarfs the difference between HHS's price and the actual sales price, and is significantly more disproportionate than the penalty struck down in *Bajakajian*. The penalty also has no aggregate limit; the tax is assessed for *each day* of noncompliance. The excise tax thus "has absolutely no correlation to any damages sustained by society or to the costs of enforcing the law," and "any relationship between the Government's actual costs and the amount of the sanction is merely coincidental." *Austin*, 509 U.S. at 621–22 & n.14 (brackets omitted).

Third, PhRMA is not aware of *any* other statute that imposes similarly severe sanctions on

comparable "misconduct." There are no other statutes that impose any penalties at all—much less crippling penalties on this scale—for the mere failure to agree to a price mandated by the government. That alone shows that the IRA's excise-tax penalty is grossly disproportionate and unconstitutional. Considered in combination with the other novel and severely punitive features of the excise "tax," this unprecedented use of "the power to destroy," *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 431 (1819), is plainly unconstitutional.

III. THE IRA VIOLATES THE DUE PROCESS CLAUSE

The Fifth Amendment provides that no person shall "be deprived of life, liberty, or property without due process of law." The government violates that prohibition where it (1) deprives a plaintiff of a protected liberty or property interest (2) without adequate procedures. *See Swarthout v. Cooke*, 562 U.S. 216, 219 (2011). Here, the IRA deprives manufacturers, providers, and patients of protected interests, while affording them no opportunity to be heard and barring judicial review.

A. The IRA Burdens Protected Interests

The "'property' interests subject to procedural due process protection are not limited by a few rigid, technical forms," *Perry v. Sindermann*, 408 U.S. 593, 601 (1972), and "extend well beyond actual ownership of real estate, chattels, or money," *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 571–72 (1972). The government can create such interests through statutes, express or implied contracts, "policies and practices," or "rules and understandings" that are "promulgated and fostered by [government] officials." *Perry*, 408 U.S. at 601–03. While the government "may elect not to confer a property interest" in the first place, "it may not constitutionally authorize the deprivation of such an interest, once conferred, without appropriate procedural safeguards." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (citation omitted).

The IRA impairs manufacturers' patent rights, as well as their right to offer access to their products at prices set by voluntary agreements.

First, Federal law provides that "patents shall have the attributes of personal property," 35 U.S.C. § 261, and more than a century ago, the Supreme Court "indisputably established" that "rights secured under the grant of letters patent … [are] property," *William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co.*, 246 U.S. 28, 39–40 (1918). The Court has reaffirmed this principle numerous times since. *See, e.g.*, *Horne v. Dep't of Agric.*, 576 U.S. 351, 359 (2015) (patent "confers upon the patentee an exclusive property in the patented invention" (quotation marks omitted)); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) ("That a patent is property … has long been settled.").

In granting property rights, "[t]he federal patent system … embodies a carefully crafted bargain"—namely, that in return for "the creation and disclosure of new, useful and nonobvious advances in technology," inventors obtain "the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). The time-limited "right to exclude" gives the patentee "pecuniary rewards," thereby "encouraging innovation. Indeed, the encouragement of investment-based risk is the fundamental purpose of the patent grant." *Biotechnology Indus. Org.* (*BIO*) *v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quotation marks omitted).

"By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the [IRA] re-balance[s] the statutory framework of rewards and incentives … as it relates to inventive new drugs." *Id.* at 1374. Because of the long lead times for developing cutting-edge medicines, manufacturers must make investment decisions based on the prospect of *future* sales. *See* Garthwaite Decl. ¶¶ 14, 18, 77(d); Costello Decl. ¶ 18; Gluck Decl. ¶¶ 14–15. For products that were patented or in development at the time of the IRA's passage, manufacturers invested in reliance on the principle that, "[u]pon grant of the patent, the only

limitation on the size of the carrot should be the dictates of the marketplace." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995); *see BIO*, 496 F.3d at 1272 ("Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts.") (citation omitted). In upending that principle, the selection of a manufacturer's drug for government price controls under the IRA deprives that manufacturer of its property rights.

Second, the IRA also disrupts the "treasured" common-law right to offer access to one's products at prices set by voluntary agreements, not government dictates. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). That right is more than "a mere subjective 'expectancy.'" *Perry*, 408 U.S. at 602. For decades, Congress and the Executive Branch allowed and encouraged manufacturers to sell their products at market prices. When Congress created Medicare Part D in 2006, Congress even *prohibited* HHS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors." 42 U.S.C. § 1395w–111(i). Manufacturers thus have a "legitimate claim of entitlement" based on years of "rules and understandings, promulgated and fostered by" the federal government. *Perry*, 408 U.S. at 602–03.

The IRA's Drug Pricing Program deprives providers and patients of protected interests as well. Providers have a protected interest in being reimbursed on a non-arbitrary basis at a lawful rate. *See Rock River Health Care, LLC v. Eagleson*, 14 F.4th 768, 774 (7th Cir. 2021); *Furlong v. Shalala*, 156 F.3d 384, 393 (2d Cir. 1998). Indeed, for some providers, the IRA threatens their "very existence and financial stability." *Accident, Injury & Rehab., PC v. Azar*, 336 F. Supp. 3d 599, 605 (D.S.C. 2018); Nyquist Decl. ¶ 10. And patients have a protected interest in making choices about their medical care, including being able to continue accessing life-sustaining medicines. *See England v. La. State Bd. of Med. Exam'rs*, 259 F.2d 626, 627 (5th Cir. 1958) (per curiam); *Andrews v. Ballard*, 498 F. Supp. 1038, 1048–51 (S.D. Tex. 1980); Nyquist Decl. ¶ 6;

Spiegel Decl. ¶ 20.

B. The IRA's Procedures Are Constitutionally Insufficient

To determine whether the government has afforded constitutionally adequate procedures under the Due Process Clause, courts balance (1) "the private interest that will be affected by the official action," (2) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards," and (3) "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement[s] would entail." *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). But where the program "provides *no process* whatsoever," the government has "a glaring problem," which "alone" compels the conclusion that it is unconstitutional. *Schepers v. Comm'r*, 691 F.3d 909, 915 (7th Cir. 2012). That is the case here, where the IRA purportedly exempts the Drug Pricing Program from notice-and-comment rulemaking, facially bars administrative and judicial review, and contains no other mechanism for manufacturers, providers, or patients to comment on, or contribute to the agency's decision-making process. Because *no* process cannot constitute *due* process, there is no need for this Court to address the full *Mathews* balancing test. But if this Court were to apply the *Mathews* test in full, the IRA flunks it.

First, the private interests at stake are indisputably weighty. Having a drug selected for "negotiation" under the IRA will have significant economic ramifications for the manufacturer. *See* Garthwaite Decl. ¶¶ 72, 102–03; Bernie Decl. ¶¶ 10, 16–17; Costello Decl. ¶¶ 18–20; Gluck Decl. ¶ 15. Indeed, in some instances, the economic viability of a product may turn *entirely* on HHS's decision whether the product is selected for "negotiation"—or is grouped with other products as one qualifying single source drug. *See* Garthwaite Decl. ¶¶ 72, 102–03; *see also* Gluck Decl. ¶ 15.

The private interests for providers and patients are similarly massive. Providers, including

NICA members, have invested enormous resources building facilities and processes for administering Medicare-reimbursed drugs effectively and efficiently. Nyquist Decl. ¶ 9. For many providers, the effect of IRA price controls on reimbursement rates may make the difference between profit and loss, or even between continuing operations and going out of business. *Id.* ¶ 10. For patients such as those served by NICA members and those represented by GCCA, the decision may be one of life and death. *Id.* ¶ 4. HHS's decisions may determine whether existing products remain available to Medicare and Medicaid beneficiaries and whether future products are brought to market for *any* patients. *Id.* ¶ 10; s*ee also* Spiegel Decl. ¶¶ 14–18.

Second, the risk of erroneous deprivation is high. According to CMS, the IRA leaves many key questions unanswered, allowing the agency to fill in the gaps. Yet CMS also maintains that the Drug Pricing Program is exempt from notice-and-comment rulemaking through 2028, and the statute purportedly bars judicial review of key implementation decisions. *See* 42 U.S.C. § 1320f note; *id.* § 1320f–7. In combination, these features mean that neither regulated entities nor the public have any right to provide views on key determinations before they are made, to have those views taken into account, or to seek judicial review after those decisions become final. Without *any* mechanism for external input or accountability—before or after implementation decisions are made—the risk of misapplying a novel, complex statutory scheme is immense.

Third, the government has no legitimate interest in insulating HHS's decision-making from input by affected parties, or in denying judicial review even for basic statutory-interpretation questions. "The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." *FDIC v. Bank of Coushatta*, 930 F.2d 1122, 1130 (5th Cir. 1991) (quotation marks omitted). Yet the IRA affords manufacturers, providers, and patients *no* opportunity to be heard on many of HHS's most consequential implementation

decisions. And this lack of process cannot be justified by any valid governmental interest. The government has identified no emergency requiring suspension of ordinary administrative processes affording input by affected parties and judicial review. Giving interested parties the opportunity to comment on decisions about the law's implementation, and to seek review of statutorily impermissible or irrational choices, would impose only minimal "fiscal and administrative burdens." *Mathews*, 424 U.S. at 335. And such external input would go a long way to reducing "the risk of an erroneous deprivation" of public and private interests. *Id.*

C. Participation in the Drug Pricing Program Is Not Voluntary

The IRA's trampling of the Due Process Clause cannot be excused on the ground that manufacturers' "participation in the Medicare program is voluntary." *Texas Clinical Labs, Inc. v. Shalala*, 1999 WL 1243200, at *4 (N.D. Tex. Dec. 21, 1999). Manufacturers spent billions of dollars developing innovative medicines long before the IRA was enacted, so it cannot be fairly said that manufacturers were "on notice" or "assumed[] the risk" that that pricing would later be decided by government *fiat*. *Id.* at *5. And there is nothing "voluntary" about being forced to choose between acceding to the government's demands on pain of massive penalties or withdrawing from nearly half of the national market for prescription drugs.

The Supreme Court rejected a similar voluntariness argument in *NFIB*. There, the Affordable Care Act attempted to coerce states into expanding their Medicaid programs by "threatening to withhold all of [their] Medicaid grants." 567 U.S. at 575. The Court found that scheme unconstitutional, rejecting the federal government's argument that states "voluntarily and knowingly accept[ed] the terms" of the Medicaid program. *Id.* at 577 (citation omitted). The seven-justice majority explained that, "[i]nstead of simply refusing to grant new funds to States that will not accept the new conditions, Congress … also threatened to withhold those States' existing Medicaid funds." *Id.* at 579–80. The sheer size of the Medicaid program, moreover, made that

threat coercive—"a gun to the head." *Id.* at 581. And Congress "surprise[ed] participating States with post-acceptance or 'retroactive' conditions," which states "could hardly anticipate" when they "developed intricate statutory and administrative regimes over the course of many decades … under existing Medicaid." *Id.* at 581, 584.

Just as the Affordable Care Act threatened to withhold *all* Medicaid funds to coerce states into accepting *new* conditions, the IRA threatens to withhold coverage for *all* of a manufacturer's drugs to coerce price concessions on *one* selected drug in an entirely *new* program. The conditions the IRA places on participation in Medicare and Medicaid thus "take the form of threats to terminate other significant independent grants." *Id.* at 580. Similarly, if withdrawing Medicaid funding was a "gun to the head" of participating states, then withdrawing coverage for all of a manufacturer's products under Medicare and Medicaid is, if anything, even more coercive. *See supra*, at 27; *cf. Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (recognizing that "total withdrawal of federal funding" can be "economic dragooning" and "a gun to the head"). And manufacturers "could hardly anticipate" that Congress would pass a draconian new price-control regime when they agreed to participate in Medicare and Medicaid and invested enormous sums to develop innovative medicines years ago. *See* Gluck Decl. ¶¶ 10, 14.

Moreover, as explained, exiting from Medicare and Medicaid does not merely create financial problems for manufacturers; it could devastate providers' and patients' access to the most-frequently prescribed medicines as well. If a manufacturer withdrew from these public insurance programs, their products would lose coverage, and beneficiaries who rely on those products—which frequently will have earned their place as "high-spend" Medicare drugs precisely because there are no satisfactory alternatives—could no longer use federal funding to access their medications. That would be devastating for millions of patients. Leaving patients with no recourse

is directly contrary to manufacturers' core mission, and it could tarnish a manufacturer's reputation in the eyes of patients and providers. *See* Garthwaite Decl. ¶ 88; Bernie Decl. ¶ 16; Costello Decl. ¶ 10; Gluck Decl. ¶ 13. That reputational harm alone could cause further, irreparable long-term financial harm. Manufacturers cannot lightly offer a cutting-edge treatment to millions of patients one day and then take it away the next. Their business relies heavily on the trust of the providers who prescribe their medicines and the patients who take them. *See id.*

In any event, manufacturers could not exit Medicare and Medicaid immediately even if they wanted to. As explained, the Medicare Part D statute delays a manufacturer's ability to terminate its relevant agreements with HHS for 11 to 23 months. *See* 42 U.S.C. §§ 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii), 1395w–153(a)(1). While CMS has represented that it will take administrative action to reduce the delay down to 30 days, *see Revised Guidance* at 120–21, manufacturers have no assurance that the agency will follow through. To begin with, CMS made these representations in the Revised Guidance, which is nonbinding. While the Revised Guidance purports to be "final" on this point, CMS previously issued parts of the Initial Guidance as "final," only to turn around and change them in the Revised Guidance.

Furthermore, CMS's statutory basis for reducing the exit delay is dubious at best and could be subject to serious challenge by providers or patients. The Part D statute contains separate provisions for termination of a manufacturer's Part D agreements—one for termination "[b]y a manufacturer" within 11 to 23 months, and another for termination "[b]y the Secretary [of HHS]" upon 30 days' notice. 42 U.S.C. § 1395w-114a(b)(4)(B)(i), (ii); *id.* § 1395w-114c(b)(4)(B)(i), (ii). The latter provision authorizes termination only "for a knowing and willful violation of the requirements of the agreement or other good cause shown." *Id.* § 1395w-114a(b)(4)(B)(i); *id.* § 1395w-114c(b)(4)(B)(i). In other words, HHS may terminate a manufacturer's agreements only

for serious misconduct. In the Revised Guidance, however, CMS asserts that it will find "good cause" at a manufacturer's request, even if it has committed no misconduct. *See Revised Guidance* at 120–21. CMS thus is seeking to rewrite the statute, transforming the provision governing HHS's termination for misconduct into an end-run around statutory limitations governing termination by a manufacturer. That flouts CMS's duty to "read the words Congress enacted in their context and with a view to their place in the overall statutory scheme." *Turkiye Halk Bankasi A.S. v. United States*, 143 S. Ct. 940, 948 (2023) (quotation marks omitted). Manufacturers accordingly must assume that termination will take up to 23 months, during which time continued participation in Medicare Part D and the IRA's Drug Pricing Program is not voluntary in any sense.

Even if CMS were authorized to reduce the delay for manufacturers to exit Medicare Part D, it remains infeasible for manufacturers to withdraw from Medicare and Medicaid. It is no secret that Medicare and Medicaid make up almost half of the national prescription drug market, which manufacturers cannot simply abandon. CMS's purported reduction is a transparent attempt to bolster the fiction that participation in the IRA's Drug Pricing Program is "voluntary" while ensuring that, in practice, manufacturers still cannot opt out. CMS's dubious assertion of authority simply confirms the agency's willingness to rewrite federal law to suit its own purposes. Finally, though patients are "voluntarily" participating in the market for lifesaving drugs, the IRA denies them procedural due process to participate in decisions that could deprive them of those drugs. *See* Spiegel Decl. ¶¶ 9, 20–22. That is all the more reason the IRA's Drug Pricing Program is unconstitutional.

CONCLUSION

For the foregoing reasons, this Court should grant summary judgment to Plaintiffs, declare the IRA's Drug Pricing Program unconstitutional, and enjoin Defendants from implementing it.

Dated: August 10, 2023 Respectfully submitted,

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